

SUMMARY OF SAFETY AND EFFECTIVENESS**1 GENERAL INFORMATION****1.1 Submitter and Owner of the 510(k)**

Garventis LLC
Ronald Reagan and International Trade Center
1300 Pennsylvania Ave., NW - Suite 700
Washington, D.C. 20004

1.2 Official Correspondent

Diane Mandell Horwitz, Ph.D., RAC
Regulatory Affairs Consultant
Mandell Horwitz Consultants, LLC
2995 Steven Martin Drive
Fairfax, Virginia 20031

Telephone: (703) 307-2921
Fax: (703) 242-1117
E-mail: dmh@mandellhorwitzconsulting.com

1.3 Date of Preparation

March 29, 2012

2 NAME OF THE DEVICE**2.1 Trade/Proprietary Name**

Hip Modular Spacer
Knee Modular Spacer

2.2 Common/Usual Name

Modular temporary hip prosthesis with gentamicin
Modular temporary knee prosthesis with gentamicin
Bone cement, antibiotic

2.3 Classification Information

Classification Name: Hip Joint Femoral (hemi-hip) Metallic Cemented or
Uncemented
Knee Joint Patellofemorotibial Polymer/Metal/Polymer
Polymethylmethacrylate (PMMA) bone cement

Classification Regulation: 21 CFR § 888.3360
21 CFR § 888.3560
21 CFR § 888.3027

Regulatory Class: Class II

Product Code: KWL, KWY
JWH
MBB

Panel: Orthopedic

3 PREDICATE DEVICES

The predicate devices are the Tecres Interspace Hip and Knee devices cleared in 510(k) submissions K101356. The predicate devices are temporary spacers that have been classified under 21 CFR § 888.3360 and 888.3560, and are Class II medical devices.

4 DESCRIPTION OF THE DEVICE

The Modular Spacers are sterile, single-use devices intended for temporary use (maximum 180 days) as joint replacements. The Hip Modular Spacer is composed of two components (a head and a stem) that are intended to be used together to form a temporary hip spacer; the components are available in a range of sizes. The Knee Modular Spacer is composed of three independent components (a femoral component, a tibial component and a tibial insert component) that are intended to be used together to form a temporary knee spacer; the components are available in a range of sizes.

The devices are made of fully formed polymethylmethacrylate (PMMA), which is radio-opaque, and contains gentamicin and color additives to give a green color.

The Modular Spacers provide a functional-mechanical mode of action; they provide patients a temporary implant allowing for a natural range of motion and partial weight-bearing during treatment. They are designed to preserve soft tissue to prevent further complications, such as muscular contraction, and to facilitate the subsequent joint replacement procedure.

5 INDICATIONS FOR USE AND INTENDED USE

The Modular Spacers have the following indications for use statements.

Hip Modular Spacer

The Hip Modular Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organisms.

The head and stem components are inserted into the acetabular cavity and femoral medullary canal, respectively, following removal of the existing acetabular and femoral components and radical debridement.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The Hip Modular Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

Knee Modular Spacer

The Knee Modular Spacer, which consists of a modular femoral, tibial and tibial insert component, is indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is applied on the femoral condyles (femoral component) and on the tibial plate (tibial component) following removal of the existing implant and radical debridement. The use of the tibial insert component is optional, when a large tibial defect is present. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The Knee Modular Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.). Because of the inherent mechanical limitations of the device materials (gentamicin/polymethylmethacrylate), the device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period.

This is the same intended use as the predicate devices. The Garventis Modular Spacers and the Tecres Interspace Hip and Knee devices are intended to be used in the same surgical procedure (two-stage revision procedure) in the same target patient population, and provide the same primary function of providing patients a temporary implant to allow for a natural range of motion and partial weight bearing.

6 TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE DATA

The Garventis Modular Spacer devices share many similar technological characteristics compared to the predicate Tecres Interspace Hip and Knee devices. The Garventis Modular Spacers and the predicate Tecres Interspace Hip and Knee share a similar size, shape and geometry, and are made from the same materials (PMMA). Each hip device also contains an inner stainless steel core for support. The Garventis Modular Spacers and the predicate Tecres Interspace Hip and Knee both incorporate gentamicin. Both devices share the same tissue contact and duration of contact. Both are provided preformed to the user, sterile, for single-use.

The design of the Hip Modular Spacer differs from the predicate device by its modular nature; it is provided as separate head and stem components, which have to be combined to achieve the final configuration of the implant. The design of the Knee Modular Spacer differs from the predicate device by its modular nature; it is provided as separate femoral and tibial components that must be coupled to achieve the final configuration of the implant. A tibial Insert is also available to be combined optionally with the Tibial component for increasing the final thickness.

The performance data presented in this 510(k) application demonstrate the substantial equivalence of the Garventis Modular Spacers to the predicate devices, and to establish that the devices are as safe and effective as the predicates.

Biocompatibility studies were conducted according to ISO 10993 to demonstrate that the device materials are safe, suitable and appropriate for their intended use.

Physical, mechanical and pharmacological testing met the acceptance criteria to demonstrate the safety and effectiveness of the Garventis Modular Spacers. Static testing (ISO 5833) and fatigue testing (ASTM F2118) were conducted of the resin; fatigue testing (ISO 7206-4, ISO 7206-6, ASTM F1800, ISO 14243-1); surface roughness testing (ISO 4287-97) of the spacer device; head size comparison and disassembly test (ISO 7206-9) of the femoral head; antibiotic elution testing and bacterial anti-adhesivity testing.

Data were presented to show the sterility of the device, the suitability and integrity of the packaging, and to support the proposed shelf life.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Garventis, LLC.
% Mandell Horwitz Consultants, LLC
Diane M. Horwitz, Ph.D., RAC
2995 Steven Martin Drive
Fairfax, Virginia 22031

APR - 5 2012

Re: K112470

Trade/Device Name: 2GC Hip Modular Spacer
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented
prosthesis
Regulatory Class: Class II
Product Code: KWL, KWY, and MBB

Trade/Device Name: 2GC Knee Modular Spacer
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis
Regulatory Class: Class II
Product Code: JWH and MBB

Dated: March 15, 2012
Received: March 16, 2012

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1-02. Indications for Use Statement

K112470
Page 1 of 2

510(k) Number: K112470

Device Names: Hip Modular Spacer

INDICATIONS FOR USE STATEMENTS

The Hip Modular Spacer, which consists of a modular head and stem, is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organisms.

The head and stem components are inserted into the acetabular cavity and femoral medullary canal, respectively, following removal of the existing acetabular and femoral components and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

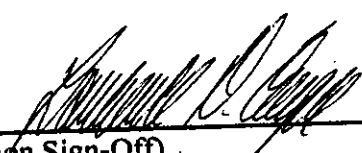
The Hip Modular Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

and/or Over the Counter Use
(21 CFR 801 Subpart C)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112470

K112470

Page 2 of 2

1-02. Indications for Use Statement

510(k) Number: K112470

Device Names: Knee Modular Spacer

INDICATIONS FOR USE STATEMENT

The Knee Modular Spacer, which consists of a modular femoral, tibial and tibial insert component, is indicated for temporary use (maximum 180 days) as an adjunct to total knee replacement (TKR) in patients undergoing a two-stage procedure due to a septic process and where gentamicin is the most appropriate antibiotic based on the susceptibility pattern of the infecting micro-organism(s).

The device is applied on the femoral condyles (femoral component) and on the tibial plate (tibial component) following removal of the existing implant and radical debridement. The use of the tibial insert component is optional, when a large tibial defect is present. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

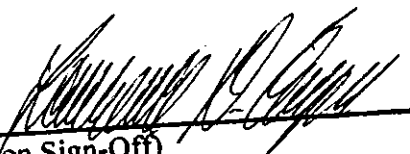
The Knee Modular Spacer is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.). Because of the inherent mechanical limitations of the device materials (gentamicin/polymethylmethacrylate), the device is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers, canes) throughout the implantation period.

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

and/or Over the Counter Use
(21 CFR 801 Subpart C)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112470